

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF TEXAS
GALVESTON DIVISION

SARAH PALMQUIST, Individually and §
as Next Friend of E.P., a Minor, and §
GRANT PALMQUIST, §
Plaintiffs, § Civil Action No. 3:21-CV-90
v. §
THE HAIN CELESTIAL GROUP, INC. §
Defendant. §
§

**DEFENDANT'S SLIDE PRESENTATION IN SUPPORT OF DEFENDANT'S
RULE 50(A) MOTION FOR JUDGMENT AS A MATTER OF LAW**

Attached as Appendix A are slides presented by Defendant The Hain Celestial Group, Inc. ("Hain") during oral argument on February 17, 2023 regarding Hain's Rule 50(a) motion for judgment as a matter of law.

DATED: February 21, 2023

Respectfully submitted,



Michael X. Imbroscio (admitted *pro hac vice*)
Phyllis A. Jones (admitted *pro hac vice*)
David N. Sneed (admitted *pro hac vice*)
Kathleen E. Paley (admitted *pro hac vice*)
Elizabeth T. Fouhey (admitted *pro hac vice*)
Nicole M. Antoine (admitted *pro hac vice*)
COVINGTON & BURLING LLP

One CityCenter
850 Tenth Street NW
Washington, DC 20001
202-662-6000
202-778-5868 [Fax]
mimbroscio@cov.com
pajones@cov.com
dsneed@cov.com
kpaley@cov.com
efouhey@cov.com
nantoine@cov.com

Brian G. Cano
State Bar No. 24045613
SDTX Bar No. 622595
FEE, SMITH & SHARP, L.L.P.
2777 Allen Parkway
Suite 800
Houston, TX 77019
713-362-8300
713-362-8302 [Fax]
bcano@feesmith.com

**ATTORNEYS FOR DEFENDANT
THE HAIN CELESTIAL GROUP, INC.**

CERTIFICATE OF SERVICE

I certify that on February 21, 2023, the foregoing was served on all counsel of record via electronic service pursuant to the Federal Rules of Civil Procedure.

/s/ *Michael X. Imbroscio*
Michael X. Imbroscio (admitted *pro hac vice*)

Appendix A

Defendant Hain's Motion For Judgment As A Matter of Law

Palmquist et al. v. The Hain Celestial Group, Inc.

February 17, 2023

NOT IN DISPUTE:

Judge has discretion to defer ruling (Opp. 1-2)

Heavy metals can be neurotoxic at some level (Opp. 3-7)

Plaintiffs do not need to identify “exact” exposure level (Opp. 3)

No dispute about volume of food eaten (Opp. 11-12)

No dispute that Dr. Nelson said what he said (Opp. 17-19)

No dispute there was no warning on Hain’s foods (Opp. 25-26)

NO EVIDENCE:

- 1. NO CAUSATION**
- 2. NOT “UNREASONABLY DANGEROUS”**

No Evidence

Plaintiffs' Response:

"nearly all the witnesses that have testified at trial admit that *any* level of heavy metals is dangerous to young, developing infants and children"

Opp. at 24

Actual Evidence:

- **NO** fact witness testified that "any level" is dangerous
- **NO** expert witness testified that "any level" is dangerous
- **NO** one disputed that all foods have trace levels of heavy metals
- **NO** witness testified that Hain's foods had higher levels than other foods

PLAINTIFFS' BURDEN: General & Specific Cause

Dkt. 132 (Order on Motions for Summary Judgment) at 8

"Cause in fact has two levels: general and specific 'General causation' is whether a substance is capable of causing a particular injury or condition in the general population,' and 'specific causation' is whether a substance caused a particular individual's injury."

Guevara v. Ferrer, 247 S.W.3d 662, 665 (Tex. 2007)

"The general rule has long been that expert testimony is necessary to establish causation as to medical conditions outside the common knowledge and experience of juror."

CAUSATION: Must Prove Harmful Level For Specific Injury

Plaintiffs' Strawman: "This Court has also recognized that '[c]onsuming heavy metals is widely known to lead to cognitive impairment, severe illness, and—at high levels—death.' ECF 132 at 3. Thus, the element of general causation is not seriously in dispute." Opp. at 4.

Proper Causation Inquiry: what *level of exposure* is *sufficient* to cause *Ethan's condition* (major neurocognitive disorder, autism, or otherwise)

Dkt. 99 (Order on Hain's Rule 702 Motions) at 7:

"[T]he Palmquists' toxicology experts do point to evidence of the "**harmful level of exposure**" needed **to establish general causation.**"

Dkt. 99 (Order on Hain's Rule 702 Motions) at 7:

"In *Curtis v. M&S Petroleum, Inc.*, the Fifth Circuit noted that the district court correctly found that the plaintiff's expert had **sufficiently defined** benzene's '**harmful level of 200–300 ppm**' by reviewing government and scientific literature."

CAUSATION: Must Prove Causation as to *Specific Injury*

Plaintiffs Resort to Overgeneralizations:

“known to cause **neurodevelopmental issues**”

Opp. at 12

“linked to **brain injuries** like the injuries in this case”

Opp. at 3.

“may increase the risk of **neurodevelopmental toxicity**”

Opp. at 5.

“adversely impact **human health**”

Opp. at 5

“linked to causing **symptoms that can present as ASD**”

Opp. at 6

“**cognitive changes** to the brain”

Opp. at 6

“**harmful**”

Opp. at 7.

“**neurobehavioral health problems**”

Opp. at 7.

Case Law:

Current v. Atochem North America, Inc., Not Reported in F.Supp.2d (2001)

“Plaintiffs' counsel argued at the hearing that the proper inquiry is whether arsenic causes cancer generically as opposed to whether arsenic causes rectal cancer. . . . [T]he **proper issue** before this Court is **not whether arsenic can cause cancer generically**, but **rather whether** it is generally accepted in the scientific community that **arsenic causes rectal cancer**.”

Current v. Atochem N. Am., Inc., 2001 WL 36101283, at *3 (W.D. Tex. Nov. 30, 2001)

was held on Defendants' Motions.

*2 I have been informed by counsel that Mr. Current lived

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CAUSATION: Must Prove *Sufficiently Harmful Level*

Case 9:20-md-02924-RLR Document 6120 Entered on FLSD Docket 12/06/2022 Page 1 of 341

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA

IN RE: ZANTAC (RANITIDINE)
PRODUCTS LIABILITY

MDL NO. 2924
20-MD-2924

"Courts universally reject general causation theories based upon the idea that any amount of a carcinogen, no matter how small, is actionable because an infinitesimal risk can neither be proven nor disproven.

Thus, since an actionable exposure threshold dose cannot, as a matter of law, be merely anything, that means it must be something provable."

In re: Zantac, MDL No. 2924, 2022 WL 17480906 (S.D. Fla. Dec. 6, 2022)

A. Plaintiffs' Internal Testing for NDMA in Ranitidine..... 39
1. Dr. Najafi and Emery Pharma's Testing..... 39

Allen v. Pennsylvania Engineering Corp., 102 F.3d 194 (1996)
65 USLW 2488, 46 Fed. R. Evid. Serv. 215, Prod. Lab. Rep. (CCH) P 14,832

102 F.3d 194
United States Court of Appeals,
Fifth Circuit.

Walter Mixon ALLEN, Jr., et al., Plaintiffs,
Mapple Gayle Allen, Barry Lane

Before WISDOM, JONES and WIENER, Circuit Judges.
Opinion
EDITH H. JONES, Circuit Judge:
Walter Allen died of a brain cancer known as glioblastoma multiforme after having been a maintenance worker at Baton

"Scientific knowledge of the **harmful level of exposure** to a chemical, plus knowledge that the plaintiff was **exposed to such quantities**, are minimal facts necessary to sustain the plaintiffs' burden. . . ."

Allen v. Pennsylvania Eng'g Corp., 102 F.3d 194, 199 (5th Cir. 1996)

plaintiffs-appellants.

Thomas E. Balhoff, Judith R. Atkinson, Roedel, Parsons, Hill & Koch, Baton Rouge, LA, Bert L. Wolff, Skadden, Arps, Slate, Meagher & Flom, New York City, for American Sterilizers Co.

Appeal from the United States District Court for the Middle District of Louisiana.

levels. First we must evaluate the trial court's evidentiary ruling under the manifest error standard, and then, with the record defined, we review *de novo* the order granting judgment as a matter of law. *Christophersen v. Allied-Signal Corp.*, 939 F.2d 1106, 1109 (5th Cir.1991) (en banc), cert. denied, 503 U.S. 912, 112 S.Ct. 1280, 117 L.Ed.2d 506 (1992). If the trial court has excluded evidence essential to maintain a cause of action, the propriety of summary

CAUSATION: No Expert Testimony On *Sufficiently Harmful Level*



Dr. Lisa Settles

"would be **outside of**" her "**expertise**", to give any opinion on **what levels of metal exposure, if any, would be necessary** to cause autism"

2/10 PM Tr. (Settles) 119:22–120:1



Dr. Stephen Nelson

"what level is the threshold to cause that injury is unknown"

2/13 AM Tr. (Nelson) at 65:3–4

"Q. You don't have an opinion or a view, based on your experience or expertise, about **what is the level of metals that might actually present a risk of heavy metal toxicity** for a child, right?"

A. **I don't** -- so the lower limit is not known."

2/13 AM Tr. (Nelson) at 64:21–65:7

CAUSATION: Differential Diagnosis Is Not a Cure-all

Johnson v. Arkema, Inc., 685 F.3d 452 (2012)
Prod.Liab.Rep. (CCH) ¶ 18,872

"[A]n expert **may not rely on a differential diagnosis** to **circumvent** the requirement of **general causation.**"

Johnson v. Arkema, Inc., 685 F.3d 452, 468 (5th Cir. 2012)

District Court for the Western District of Texas, Walter S. Smith, Jr., J., granted summary judgment in favor of manufacturer, and plaintiff appealed.

ISSUE AND RATIONALE: THE APPELLANT CHALLENGED THE DISTRICT COURT'S GRANTING OF SUMMARY JUDGMENT IN FAVOR OF THE DEFENDANT. THE APPELLANT CLAIMED THAT THE DISTRICT COURT ERRED IN (1) GRANTING SUMMARY JUDGMENT IN FAVOR OF THE DEFENDANT BECAUSE THE PLAINTIFF WAS UNABLE TO PROVE CAUSATION *457 WITHOUT THE OPINIONS

"[A]fter conducting a differential diagnosis, the expert diagnosed the plaintiff with RADS. . . . The expert also concluded that the plaintiff's RADS was caused by certain chemicals to which the plaintiff was exposed based on his **analysis of MSDS warnings**, his **examination and testing of the plaintiff**, and the **close temporal proximity** between the plaintiff's exposure and subsequent injury. . . . Despite the expert's differential diagnosis, we held that the district judge did not abuse its discretion in excluding the expert's causation testimony because he **failed to present reliable scientific support showing that the chemicals at issue could actually cause RADS.**"

Plaintiff-Appellant.

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CAUSATION

Plaintiffs' Fifth Circuit and Texas cases highlight Plaintiffs' failure of proof:

- ***Curtis v. M&S Petroleum, Inc., 174 F.3d 661, 671 (5th Cir. 1999) (causation)***
 - "Dr. Stevens testified that the refinery workers were exposed to levels of benzene that were several hundred times above the permissible exposure level of 1 ppm"
- ***O'Neill v. Seariver Mar., Inc., 246 F. App'x 278, 280 (5th Cir. 2007) (Jones Act – causation)***
 - "expert witness provided an opinion that a vapor at that location would have been greater than 200 ppm"
- ***Knight v. Kirby Inland Marine Inc., 482 F.3d 347, 355 (5th Cir. 2007) (no causation)***
 - "although the 1970 phase of the Nilsson study could arguably support the theory that benzene can generally lead to Hodgkin's lymphoma, it would not support the conclusion that it led to Hodgkin's lymphoma in Knight's case"
- ***McManaway v. KBR, Inc., 852 F.3d 444, 453 (5th Cir. 2017) (no causation)***
 - "used these control numbers to put each plaintiff into an 'exposure category'" and "gauged whether Plaintiffs' injuries were caused by sodium dichromate based on the assigned exposure categories"

CAUSATION: Expert Opinion On Exposure Levels Required

Plaintiffs' Claim:

Case 3:21-cv-00090 Document 167 Filed on 02/16/23 in TXSD Page 15 of 36

"Plaintiffs' clinical experts applied the same professional standards in the courtroom that they apply in their **clinical practice to rule out other plausible causes**—which is why this Court found their testimony to be admissible. This sort of clinically reliable analysis is just what the Fifth Circuit contemplates with its rule that **[c]ircumstantial evidence** can be used to establish injurious exposure.' **O'Neill, 246 Fed. App'x. at 279-80.**"

Opp. at 12-13.

Case Law:

"The standard for causation in **Jones Act** cases is 'very light.'"

V.
PENNSYLVANIA ENGINEERING
(CORP., et al., Defendants,

worked several hospitals for over 20 years. During that time, he occasionally replaced cylinders containing ethylene oxide ("EtO"), a chemical that has been widely used in this country for sterilization of medical equipment and medical

"Circumstantial evidence can be used to establish injurious exposure In Oman, O'Neill saw a plum of vapor when he was **gauging and sampling. An expert witness provided an opinion that a vapor at that location would have been greater than 200 ppm.**"

O'Neill v. Seariver Mar., Inc., 246 F. App'x 278, 280 (5th Cir. 2007)

CAUSATION

Plaintiffs' Fifth Circuit and Texas cases highlight Plaintiffs' failure of proof:

- ***Johnson v. Arkema, Inc., 685 F.3d 452, 472 (5th Cir. 2012) (no causation)***
 - "Johnson does not offer any evidence that the actual amounts of tin oxide to which he was exposed were of a sufficient concentration level to cause his restrictive lung disease and pulmonary fibrosis"
- ***Coastal Tankships, U.S.A., Inc. v. Anderson, 87 S.W.3d 591, 609 (Tex. App. 2002) (no causation)***
 - "Dr. Miller's testimony provided nothing outside his differential diagnosis except the temporal proximity of the naphtha fumes to Anderson's symptoms. Dr. Miller admitted that he was not a toxicologist, did not know what chemicals comprised naphtha, and had read no literature connecting naphtha and BOOP"
- ***Clark v. Kellogg Brown & Root L.L.C., 414 F. App'x 623, 628–29 (5th Cir. 2011) (Jones Act – causation)***
 - "Clark's expert witnesses testified that the increase in relative risk of AML from benzene exposure was statistically significant at levels of exposure in the single digits of ppm-years"
- ***Silverman v. Watson Pharms., Inc., No. CIV.A. H-10-1952, 2013 WL 1645771, at *1 (S.D. Tex. Apr. 16, 2013) (no summary judgment)***
 - "Plaintiffs retained Dr. Ernest Lykissa—a forensic toxicologist—to testify regarding the results of the lab test results and Mrs. Silverman's condition"

CAUSATION: Expert Opinion On Exposure Levels Required

Plaintiffs' Claim:

Case 3:21-cv-00090 Document 167 Filed on 02/16/23 in TXSD Page 15 of 36

same professional standards in the courtroom that they apply in their clinical practice to rule out other plausible causes—which is why this Court found their testimony to be

"The principle recognized by the Fifth Circuit in **Clark**—namely, that **causation can be established** in certain cases **without quantification of the dose levels** at which exposure to a substance causes an injury and qualification of the dose incurred by the plaintiff—is hardly novel."

Opp. at 13 (citing *Clark v. Kellogg Brown & Root L.L.C.*).

the plaintiff—is hardly novel. The most recent version of the Federal Judicial

Case Law:

"**Clark's expert witnesses testified** that the increase in relative **risk** of AML from benzene exposure was **statistically significant at levels of exposure in the single digits of ppm-years**; . . . Taking that evidence together with the experts' **testimony correlating symptoms with particular exposure levels** and identifying the relatively low exposure levels known to be hazardous, the district court found that 'it is more likely than not that Mr. Clark was exposed to benzene at hazardous levels.'"

Clark v. Kellogg Brown & Root L.L.C., 414 F. App'x 623, 628–29 (5th Cir. 2011)

Silverman v. Watson Pharms., Inc., 2013 WL 1681470 (S.D. Tex. Apr. 17, 2013)

Silverman v. Watson Pharmaceuticals, Inc., Not Reported in F.Supp.2d (2013)
2013 WL 1681470

2013 WL 1681470
Only the Westlaw citation is currently available.
United States District Court,
S.D. Texas,
Houston Division,
Bailey SILVERMAN and Louis Silverman, Plaintiffs,
v.
WATSON PHARMACEUTICALS,
INC., et al., Defendants,
Civil Action No. H-10-1952,
April 17, 2013.

Attorneys and Law Firms
John T. Boundas, Margaret Ellen Leacocke, Williams Kherkher et al., Houston, TX, for Plaintiffs.

Michael A. Walsh, Strasburger Price LLP, Dallas, TX, Charles Brannon Robertson, Robert Bruce Hurley, Jr., Thomas Michael Gutting, King & Spalding, LLP, Houston, TX, Chilton Varner, King & Spalding, Atlanta, GA, for Defendants.

MEMORANDUM OPINION & ORDER

GRAY H. MILLER, District Judge.

*1 Pending before the court is defendants' Watson Pharmaceuticals, Inc. and Watson Pharma, Inc.'s (collectively "the Watson defendants") motion for summary judgment on causation (Dkt. 71). Upon consideration of the motion, the response, the reply, the summary judgment record, counsels' arguments at a hearing on this matter, and the applicable law, the motion is DENIED.

BACKGROUND

The court adopts the facts as related in its order on defendant Capsugel, Inc.'s motion for summary judgment on causation (Dkt. 116) and adds the following facts:

Although Bailey Silverman began taking Taztia XT in September 2008, she did not save any of her medication for testing until her last refill on December 29, 2008, Dkt.

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482 F.3d 408,
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E.3d 388, 392

"Last, the Watson **defendants argue that there is no evidence** that (1) their product was the substantial factor that caused Mrs. Silverman's illness; (2) Mrs. Silverman **was exposed to harmful inorganic arsenic**; and (3) the Watson defendants' **product contained harmful inorganic arsenic.**"

"The Watson defendants' arguments that Mrs. Silverman cannot demonstrate that she ingested harmful inorganic arsenic or that the Watson defendants' product contained harmful inorganic arsenic. . . . **Plaintiffs' forensic toxicology expert, Dr. Lykissa, testified** that not all organic arsenic is innocuous. . . . He further testified that the human body can process inorganic arsenic in such a way that it will appear organic when excreted in urine."

CAUSATION: Expert Opinion On Exposure Levels Required

Plaintiffs Recognized Necessity:

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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF TEXAS

Dkt. 65 (Plaintiffs' Opp. to Hain's 702) at 3:

"The **precise levels** of heavy metals in Hain's products consumed by Ethan during his critical period of neurodevelopment are **unknown** and unknowable. **Plaintiffs' toxicology experts therefore offered estimates of Ethan's exposure.** In the absence of better data, such estimates are appropriate and helpful."

This Court Agreed:

Case 3:21-cv-00090 Document 99 Filed on 12/28/22 in TXSD Page 1 of 13

United States District Court
Southern District of Texas
ENTERED
December 28, 2022

Dkt. 99 (Order on Hain's Rule 702 Motions) at 12:

"The information in **Dr. Parran's report** is important because it provides helpful information to the jury **about Ethan's consumption patterns.**"

genetics experts' testimony, Dkts. 51, 61. For the reasons set forth below, the court denies the motions.

I. THE MOTIONS TO EXCLUDE

A. Hain's Motions to Exclude Expert Testimony on Causation

Hain moved separately to exclude expert testimony on general causation, Dkt. 50, and specific causation, Dkt. 53.

CAUSATION: No Expert Testimony On Ethan's Exposure

No toxicologist testified for Plaintiffs



Dr. Stephen Nelson

did not "do any kind of testing, analysis, mathematical calculations . . . to determine whether there were, in fact, heavy metals in what Ethan ate"

2/13 AM Tr. (Nelson) 64:11–15

No Dr. Parran, No Dr. Aschner



Dr. Lisa Settles

did not "does not "know one way or the other whether there were heavy metals in any of the specific foods that Ethan ate"

2/10 PM Tr. (Settles) 99:12–15



Mr. Seshagiri Rao

"defer[s] to the other experts in the case" as to "whether [Ethan's load of heavy metals] was **caused by baby food or some other exposure**"

2/13 PM Tr. (Rao) 74:6–13

CAUSATION: Post-Hoc Gap-Filling

Plaintiffs' Explanation: "Hain did not test its baby food for heavy metals during the relevant period" (Opp. 22)

- **Facts:** Ingredient testing going back to 2011 (Ex. P-1287, Ex. HAIN-396)
- **Facts:** Finished product data for 2016-2017, 2019, 2020-2021, 2021 on (Ex. P-1288, Ex. HAIN-0384, Ex. HAIN-0205, Ex. HAIN-0201)

Plaintiffs' Explanation: "there is no question that Hain's baby food carried an inherent risk of heavy-metals toxicity arising out of Hain's ingredients, specifications, and testing standards" (Opp. 24)

- **Facts:** No expert testified to this

Plaintiffs' Explanation: "the evidence has shown that these quantities of heavy metals were far above any safe line" (Opp. 11)

- **Facts:** No expert testified to this

No Evidence Hain's Foods Unreasonably Dangerous

NO expert testified that Earth's Best is different from baby food or grocery store produce:

- Overwhelming evidence is that levels in Earth's Best are consistent with other baby food brands
- Overwhelming evidence is that levels in Earth's Best are consistent with fresh produce and grains
- No expert testified that something about Earth's Best was different

No Evidence

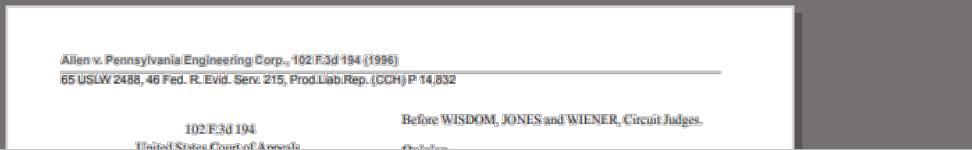
NO Expert Testimony On Harmful Levels

NO Expert Testimony On Ethan's Exposure

NO Evidence Hain's Products Were Unsafe

NO EVIDENCE: Marketing Defect

Expert Testimony Required:

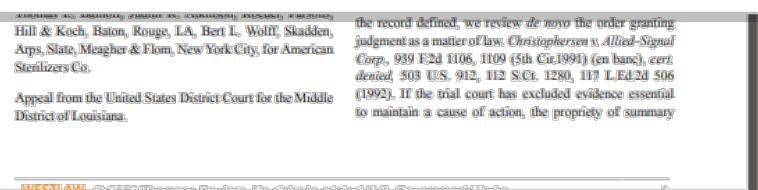


"[O]ur review of Texas case law demonstrates a consensus that **expert testimony is required** in the context of strict liability **marketing defect** claims"

Ethicon Endo-Surgery, Inc. v. Gillies, 343 S.W.3d 205, 211 (Tex. App.—Dallas 2011, pet. denied)

Plaintiffs' Record:

NO Expert Testimony On Marketing Defect



NO EVIDENCE: Manufacturing Defect

Expert Testimony Required:

Allen v. Pennsylvania Engineering Corp., 102 F.3d 194 (1996)
65 USLW 2488, 46 Fed. R. Evid. Serv. 215, Prod. Lab. Rep. (CCH) P 14,832

102 F.3d 194
United States Court of Appeals,
Fifth Circuit.

Before WISDOM, JONES and WIENER, Circuit Judges.
Opinion

"Expert testimony is generally necessary to show that a product was defectively designed, manufactured, or marketed."

Sigurdson v. Ford Motor Co., No. CIV.A.H-04-03429, 2006 WL 417502, at *2 (S.D. Tex. Feb. 21, 2006)

Arps, Slate, Meagher & Flom, New York City, for American Sterilizers Co.

Appeal from the United States District Court for the Middle District of Louisiana.

Judgment as a matter of law. *Christophersen v. Allied-Signal Corp.*, 939 F.2d 1106, 1109 (5th Cir.1991) (en banc), cert. denied, 503 U.S. 912, 112 S.Ct. 1280, 117 L.Ed.2d 506 (1992). If the trial court has excluded evidence essential to maintain a cause of action, the propriety of summary

Plaintiffs' Record:

NO Expert Testimony on Manufacturing Defect